

SYMPOSIUM: RECENT ADVANCES IN AMPUTATION SURGERY AND REHABILITATION

How Does Ankle-foot Orthosis Stiffness Affect Gait in Patients With Lower Limb Salvage?

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Abstract

Background Ankle-foot orthoses (AFOs) are commonly prescribed during rehabilitation after limb salvage. AFO stiffness is selected to help mitigate gait deficiencies. A new custom dynamic AFO, the Intrepid Dynamic

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Exoskeletal Orthosis (IDEO), is available to injured service members but prescription guidelines are limited.

Questions/purposes In this study we ask (1) does dynamic AFO stiffness affect gait parameters such as joint angles, moments, and powers; and (2) can a given dynamic AFO stiffness normalize gait mechanics to noninjured control subjects?

Methods Thirteen patients with lower limb salvage (ankle arthrodesis, neuropathy, foot/ankle reconstruction, etc) after major lower extremity trauma and 13 control subjects who had no lower extremity trauma and wore no orthosis underwent gait analysis at a standardized speed. Patients wore their custom IDEO with posterior struts of three different stiffnesses: nominal (clinically prescribed stiffness), compliant (20% less stiff), and stiff (20% stiffer). Joint angles, moments, powers, and ground reaction forces were compared across the varying stiffnesses of the orthoses tested and between the patient and control groups. Results An increase in AFO compliance resulted in 20% to 26% less knee flexion relative to the nominal (p = 0.003)and stiff (p = 0.001) conditions, respectively. Ankle range of motion and power generation were, on average, 56% (p < 0.001) and 63% (p < 0.001), respectively, less than controls as a result of the relatively fixed ankle position. Conclusions Patients with limb salvage readily adapted to different dynamic AFO stiffnesses and demonstrated few

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Form Approved OMB No. 0704-0188 biomechanical differences among conditions during walking. None of the stiffness conditions normalized gait to controls.

Clinical Relevance The general lack of differences across a 40% range of strut stiffness suggests that orthotists do not need to invest large amounts of time identifying optimal device stiffness for patients who use dynamic AFOs for low-impact activities such as walking. However, choosing a stiffer strut may more readily translate to higher-impact activities and offer less chance of mechanical failure.

Introduction

The majority of combat-related injuries sustained during Operations Iraqi Freedom and Enduring Freedom involve the extremities [30]. These extremity injuries are often the result of explosive mechanisms (52%), gunshots (16%), or mortar attacks (9%) [30]. Advances in surgical procedures [34] and rehabilitation [7, 31, 32] have improved the ability to salvage the limb and restore function after severe injury. Limb salvage, or reconstruction, is a viable treatment option for many patients with severe limb trauma who would otherwise undergo amputation [34]. However, many patients still are unable to return to full functional capacity as a result of muscle loss [17], instability, stiffness, chronic pain, and peripheral nervous system injury.

Ankle-foot orthoses (AFOs) commonly are prescribed to provide mechanical support to the salvaged limb during walking and other functional tasks. The external support provided can enhance performance outcomes [4, 14 16, 33, 40] and stability [23] by counteracting joint torque [20] and improving proprioception [19] to reduce injury [37]. Although the majority of AFO research is conducted using populations with myelomeningocele, spastic diplegia, hemiparesis, and multiple sclerosis, a common feature of AFO use in these populations and those with limb salvage is plantarflexor weakness. Gait is hindered by limited plantarflexor power [26, 27] for which the hip generally compensates [24, 26]. The resulting gait is mechanically inefficient [8, 22] and leads to elevated energy cost [29, 39]. Most passive-dynamic AFOs help compensate by functioning as a spring that stores energy when initially deformed in midstance and returns energy at the end of stance [2, 12, 42]. The stiffness of a dynamic AFO can be optimized to alleviate gait-related problems [4, 18, 36] because it determines the extent to which the AFO maintains the ankle in a neutral position, provides mediolateral stability, and aids propulsion through energy storage and return mechanisms [25, 36].

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The biomechanical effects of dynamic AFO use after lower extremity trauma have not been widely reported. Patzkowski et al. [33] was the first to compare three different dynamic AFOs during performance tasks in military patients with limb salvage. These AFOs were the posterior leaf spring, Blue Rocker (Allard USA Inc, Rockaway, NJ, USA), and a new custom dynamic AFO available to wounded warriors called the Intrepid Dynamic Exoskeletal Orthosis (IDEO, patent pending #20120271214). The IDEO offered functional and performance improvements over the other AFOs and several patients decided against limb amputation after rehabilitation with the IDEO. The IDEO mechanically compensates for insufficient ankle function (for example, the semirigid nature of the IDEO can compensate for a completely flaccid ankle) and has enabled wounded service members to return to high levels of physical activity [32]. The stiffness of the IDEO, which affects its energy storage and return capabilities, is expected to play a large role in device functionality, but this has not been studied. In addition, despite functional and performance improvements in this patient population using the IDEO compared with other devices, it remains unknown if this dynamic AFO can restore normal gait mechanics.

Therefore, the overall purpose of this study was to determine the effect of dynamic AFO stiffness on lower extremity kinematics and kinetics in injured service members who had undergone lower limb salvage. Specifically, the first aim was to determine if AFO stiffness affected biomechanical parameters of walking such as joint angles, moments, and powers. The second aim was to determine if a given stiffness could normalize these gait parameters to control subjects.

Patients and Methods

This study used a repeated-measures, controlled study design to address the two aims. Thirteen male patients with traumatic, unilateral lower limb reconstruction gave written informed consent to participate in the study. The number of subjects was determined from preliminary data using a power of 0.80, an alpha of 0.05, and the ability to detect a difference of 0.56 W/kg in ankle power generation at pushoff [41]. Mechanisms of injuries included motor vehicle accidents, gunshot wounds, and blasts. As a result of these injuries, patients were frequent or constant users of a custom IDEO ankle foot orthosis (Fig. 1). All patients were under the care of the same certified orthotist, had sustained functional limitations associated with traumatic lower limb injury, were ambulatory without assistive devices other than an AFO, and were capable of completing the study protocol. Inclusion criteria involved the





Fig. 1 The custom IDEO was constructed and fit by the same prosthetist/orthotist for all limb salvage patients. The IDEO consists of a carbon fiber distal supramalleolar footplate, a proximal ground reaction cuff, and a removable, connective, posterior mounted strut. A foam heel wedge of varying heights was often placed beneath the heel at the recommendation of the prosthetist/orthotist. The height of the wedge was consistent across testing conditions.

ability to walk, run, perform agility-based movements during running, and climb stairs in the IDEO. Thirteen men with no history of lower extremity trauma served as a control group to provide normative walking data and walked without external or in-shoe orthoses. Subject groups were not different in height (p = 0.682) or body mass (p = 0.787) but the control group was, on average, 6 years younger (p = 0.005) (Table 1).

The experimental setup consisted of a 26-camera motion capture system (120 Hz; Motion Analysis Corp, Santa Rosa, CA, USA) with five centrally located force platforms in tandem along a walkway (1200 Hz; AMTI, Watertown, MA, USA). Fifty-seven retroreflective markers were secured to anatomical landmarks and segments of the upper and lower extremities, head, trunk, and pelvis. Rigid plates of markers were secured to the thighs and lower legs for tracking purposes [41] (Fig. 2). A digitization pointer consisting of four markers was used to identify 20 anatomical landmarks in relation to marker clusters (C-Motion, Inc, Germantown, MD, USA).

Subjects participated in three overground walking sessions on separate days. Stiffness of the IDEO was modified by altering the stiffness of the posterior strut component. Custom struts were manufactured specifically for study purposes to allow the assessment of three conditions: (1)

nominal (clinically prescribed stiffness as fit by the prosthetist/orthotist); (2) compliant (20% more compliant than the nominal strut); and (3) stiff (20% stiffer than the nominal strut). Clinical prescription of strut stiffness was based on the patient's available range of motion (ROM), activity level, types of activities performed, body mass, and active duty status (ie, indicating that they would carry heavy loads on a regular basis). All struts were initially designed in SolidWorks (Waltham, MA, USA) and constructed from Unfilled Nylon 11 powder (PA D80-ST; Advanced Laser Materials, Temple, TX, USA) using a selective laser sintering technique previously described [13, 35]. Mechanical testing performed before biomechanical testing ensured the struts were within 5% of their intended stiffness. Mechanical testing indicated that the nominal struts ranged in stiffness from 50 kgf/mm to 105 kgf/mm with mean (SD) values of 77 (19) kgf/mm. The constructed struts were affixed to the posterior aspect of the IDEO's footplate and connected the rigid carbon fiber footplate to the upper tibial cuff. Strips of lead tape (ClubmakerTM; Golfsmith, Austin, TX, USA) were added along the entire lengths of the nominal and compliant struts to match the mass of the stiff strut. Then, patient participants were their IDEO for at least 30 minutes before data collection. The footwear worn by patients was standardized among the three sessions but shoe makes and models were not standardized between subjects or between groups. Patients were not informed which strut they were wearing, and the order of the conditions was randomized. Patient preference for strut stiffness was recorded after the final testing session at which time subjects indicated which strut they preferred for daily use.

Three-dimensional marker and analog data were recorded as subjects walked across the force platforms at a standardized velocity. This velocity (\pm 5%) was calculated from the forward progression of a marker on the seventh cervical vertebrae and corresponded to a dimensionless Froude number of 0.16 [38]. Self-selected walking velocity was also recorded as a descriptive characteristic. Five strides from the IDEO side were analyzed (Visual3DTM, Version 4.96; C-Motion, Inc, Germantown, MD, USA). Marker and analog data were interpolated using a cubic spline and filtered using a fourth-order Butterworth lowpass filter with cutoff frequencies of 6 and 50 Hz, respectively.

A 15-segment, full body model was created in Visual3D and used in subsequent analyses [11]. Sagittal plane ankle, knee, and hip angles were calculated. To control for any subtle alignment changes when struts changed, ankle angles were scaled to the value at 75% of swing, when the ankle maintained a relatively fixed position within the IDEO. Internal joint moments were calculated from a standard inverse dynamics approach and then resolved into



Table 1. Mean (SD) subject characteristics

Group	Age (years)	Height	Mass	Months of IDEO use	Diagnosis
IDEO					
1	28	1.92	96.4	3.9	R LE neuropathy
2	21	1.79	95.7	11.3	R paresis
3	30	1.78	97.3	7.5	R LE tissue loss/trauma
4	40	1.81	81.0	9.3	L ankle fracture and osteoarthritis
5	30	1.75	79.1	9.8	L tibia/fibula fracture
6	30	1.76	78.2	11.0	L LE neuropathy, crushed tibia/fibula
7	36	1.78	75.5	4.4	L LE talar fracture, multiple fractures
8	22	1.64	80.3	9.0	R LE tissue loss/trauma
9	27	1.82	92.0	6.4	R equinovarus, LE tissue loss/trauma, neuropathy
10	23	1.74	84.1	5.0	L LE tibia/fibula fracture
11	36	1.95	80.9	20.8	L LE fractures, shrapnel, vascular injury
12	33	1.77	92.0	11.3	L tibia fracture, R distal femur fracture
13	26	1.86	113.6	11.2	L LE neuropathy
Mean (SD)	29.4 (4.6)	1.80 (0.08)	88.2 (10.8)	8.1 (5.2)	
Control					
1	23	1.87	101.8		
2	29	1.74	100.2		
3	22	1.73	99.5		
4	20	1.82	79.5		
5	23	1.80	76.1		
6	30	1.78	76.5		
7	22	1.76	76.0		
8	19	1.74	73.6		
9	21	1.81	84.5		
10	21	1.78	82.0		
11	18	1.90	81.1		
12	21	1.82	93.4		
13	32	1.98	106.3		
Mean (SD)	23.1 (4.4)	1.81 (0.07)	87.0 (11.6)		
p value	0.005	0.682	0.787		

IDEO = Intrepid Dynamic Exoskeletal Orthosis; R = right; L = left; LE = lower extremity. Months ambulating characterizes the months ambulating in the IDEO.

their sagittal plane component and scaled to body mass. Lastly, joint powers were scaled to body mass and ground reaction forces were scaled to body weight. All dependent measures were normalized to 101 data points and represented as percent of stride.

Peak ankle, knee, and hip angles, internal moments and powers, and ground reaction forces were calculated (Matlab Version 7.14; The Mathworks, Inc, Natick, MA, USA) and included in the statistical analysis (Version 19; SPSS Inc, Chicago, IL, USA). To address the first aim, comparisons were made among the three stiffnesses of the orthoses tested using a one-way analysis of variance (ANOVA) and Huynh-Feldt corrections. Post hoc paired ttests with Bonferroni-Holm correction factors were used to identify differences between stiffnesses. To address the

second aim, comparisons between AFO users who had undergone limb salvage surgery after major lower extremity trauma and control subjects were tested using a one-way ANOVA with Dunnett's post hoc tests. The unadjusted criterion for statistical significance was set at p < 0.05.

Results

Aim 1: Comparisons Among Stiffnesses

Subject preference for the three strut stiffnesses varied. Three subjects preferred the stiff strut, five preferred the nominal, three preferred the compliant, one preferred



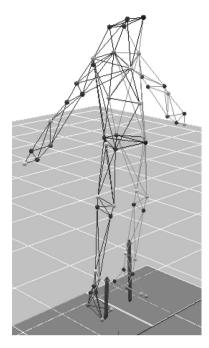
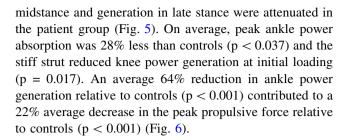


Fig. 2 Fifty seven markers were used to create the body segments. A digitization pointer was used to identify anatomical landmarks of the ankles, knees, shoulders, and elbows.

nominal and stiff equally, and one could not discern any difference. Temporal spatial parameters of gait, including self-selected walking velocity, were not different among strut conditions (Table 2). Dynamic AFO stiffness influenced walking mechanics not at the ankle, but at the knee. Use of a 20% more compliant strut than prescribed resulted in a 20% decrease in stance phase knee flexion relative to the nominal strut (p = 0.003) and a 26% decrease relative to the stiff strut (p = 0.001) (Fig. 3; Table 2). Moreover, the peak internal knee extensor moment during stance was greater in the stiff strut compared with the nominal (p = 0.004) (Fig. 4). Stiffness did not affect peak joint powers (Fig. 5) or peak ground reaction forces (Fig. 6).

Aim 2: Comparisons Between Groups

Patients who used semirigid AFOs after limb reconstruction surgery exhibited gait deviations relative to ablebodied control subjects. None of the stiffnesses entirely normalized ankle, knee, or hip kinematics to controls (Fig. 3). Ankle and knee motion were more limited in the patient group and patients wearing the semirigid IDEO had, on average, 16 fewer degrees of available ankle ROM (p < 0.001) and 10 fewer degrees of knee ROM across the gait cycle than controls (p < 0.001) (Table 2). The hip compensated for some of the limitations in the other joints by increasing peak flexion during stance an average of 26% relative to controls (p < 0.013). Ankle power absorption in



Discussion

The stiffness of a dynamic AFO plays a role in how it stores and returns energy during the gait cycle. However, it was unknown if certain stiffness parameters for AFOs worn by individuals with traumatic lower limb salvage could begin to normalize ankle, knee, and hip mechanics to ablebodied individuals. The primary purpose of this study was to determine the effect of AFO stiffness on biomechanical parameters of walking in patients with lower limb reconstruction. The secondary purpose was to compare gait parameters with control subjects.

This study had several limitations. Some of the gait limitations found in the IDEO condition relative to controls may have been influenced by the use of a very supportive AFO or may have resulted from the injury and/or surgical procedures themselves. Because it was not possible for many subjects to complete a gait analysis without their IDEO, no conclusions can be made regarding the specific effect of IDEO use compared with an unbraced condition. These comparisons are potentially interesting but may not have real-world relevance because patients depended on its external support for mobility. In addition, although the injuries sustained by the subjects were heterogeneous, between-subject variability in the patient group was not beyond that of noninjured individuals. Thus, although injuries, and possibly also ankle strength and ROM, differed within the patient group, these factors did not likely affect gait mechanics or the overall interpretation of the results of the study. Also, self-selected walking velocity is an indicator of recovery during rehabilitation after lower limb trauma [1] and velocities were not significantly different between the patient and control groups. Therefore, the patients may have attained a level of functional recovery where relevant comparisons could be made to control subjects during walking. The final limitation is that high-impact activities, where stiffer AFOs may offer more appropriate energy storage and return and reduce the risk of mechanical failure, were not tested.

Strut stiffness had some effects on gait. An increase in AFO compliance increased the stiffness at the knee because the knee underwent less flexion when the compliant strut was worn relative to the nominal and stiff. In



Table 2. Mean (SD) temporal spatial parameters, peak kinematics, and peak kinetics for the IDEO limb

Parameters, kinematics, and kinetics for the IDEO limb	Compliant (^C)	Nominal (^N)	Stiff (^S)	Control (*)
Temporal spatial				
Self selected velocity (m/s)	1.27 (0.15)	1.29 (0.12)	1.27 (0.15)	1.21 (0.11)
Stride length (m)	1.46 (0.09)	1.46 (0.09)	1.45 (0.08)	1.43 (0.07)
Stride time (s)	1.16 (0.07)	1.14 (0.06)	1.16 (0.09)	1.17 (0.06)
Stride width (m)	0.14 (0.03)	0.14 (0.06)	0.14 (0.01)	0.13 (0.03)
Kinematics (degrees)				
Ankle				
Peak dorsiflexion during stance	6.64 (2.20)*	5.85 (2.28)*	5.68 (2.09)*	15.88 (2.48)
Peak plantarflexion during late stance	-0.56 (0.57)*	-0.58 (0.47)*	-0.34 (0.44)*	12.08 (3.53)
Range of motion	13.38 (4.42)*	12.32 (3.22)*	11.90 (3.69)*	28.18 (3.57)
Knee				
Peak flexion during stance	12.60 (7.19) ^{SN}	15.85 (6.18) ^C	17.02 (7.36) ^C	13.12 (7.51)
Range of motion	61.32 (3.92)*	61.47 (4.30)*	61.47 (4.30)*	71.78 (3.48)
Hip				
Peak flexion in stance	34.46 (4.85)*	35.97 (5.91)*	36.23 (3.09)*	28.28 (6.69)
Peak extension	-4.93 (5.06)	-3.63 (6.21)	-3.49 (3.04)*	-8.66 (6.27)
Range of motion	40.75 (4.45)	40.98 (4.23)	40.87 (4.24)	39.67 (2.72)
Moments (Nm/kg)				
Ankle				
Peak dorsiflexion in early stance	0.36 (0.12)*	0.38 (0.09)*	0.39 (0.07)*	0.24 (0.05)
Peak plantarflexion	-1.47 (0.24)	-1.51 (0.23)	-1.48 (0.23)	-1.48 (0.08)
Knee				
Peak extensor during stance	$0.41 (0.23)^{S}$	0.50 (0.22)	$0.58 (0.24)^{\text{C}}$	0.48 (0.23)
Peak flexor during late stance	-0.46 (0.20)	-0.43 (0.19)	-0.40 (0.17)	-0.31 (0.10)
Hip				
Peak extensor in early stance	0.90 (0.26)	0.98 (0.24)	0.93 (0.24)	1.03 (0.29)
Peak flexor	-0.68 (0.21)	-0.67(0.20)	-0.65 (0.22)	-0.67 (0.21)
Powers (W/kg)				
Ankle				
Peak absorption in initial loading	-0.33(0.11)	-0.34 (0.10)	-0.33(0.11)	-0.37 (0.16)
Peak absorption in midstance	-0.84 (0.35)*	-0.84 (0.28)*	-0.80 (0.31)*	-1.15(0.29)
Peak generation in late stance	0.96 (0.46)*	0.86 (0.32)*	0.85 (0.36)*	2.50 (0.47)
Knee				
Generation at initial loading	0.80 (0.43)	0.79 (0.33)	0.71 (0.32)*	1.20 (0.60)
Absorption in early stance	-0.41 (0.21)	-0.49~(0.28)	-0.60 (0.35)	-0.61 (0.42)
Generation after loading response	0.65 (0.36)	0.67 (0.39)	0.59 (0.20)	0.47 (0.20)
Hip				
Peak generation in early stance	0.77 (0.22)	0.81 (0.34)	0.82 (0.34)	0.60 (0.29)
Peak absorption in late stance	-0.52 (0.21)	-0.55 (0.21)	-0.49(0.20)	-0.49 (0.18)
Peak generation in late stance	0.84 (0.22)	0.87 (0.19)	0.87 (0.19)	0.78 (0.20)
Ground reaction force (x body weight)				
First peak vertical	1.06 (0.06)	1.09 (0.06)	1.07 (0.05)	1.08 (0.03)
Second peak vertical	1.04 (0.07)	1.05 (0.08)	1.05 (0.07)	1.07 (0.06)
Peak breaking	-0.13 (0.03)	-0.14 (0.03)	-0.14 (0.03)	-0.17 (0.04)
Peak propulsive	0.15 (0.03)*	0.15 (0.03)*	0.15 (0.03)*	0.19 (0.02)
Peak medial/lateral	0.07 (0.01)	0.07 (0.02)	0.07 (0.01)	0.07 (0.02)

^{*} Difference from control subjects; N = difference from nominal; S = difference from stiff, C = difference from compliant; IDEO = Intrepid Dynamic Exoskeletal Orthosis.



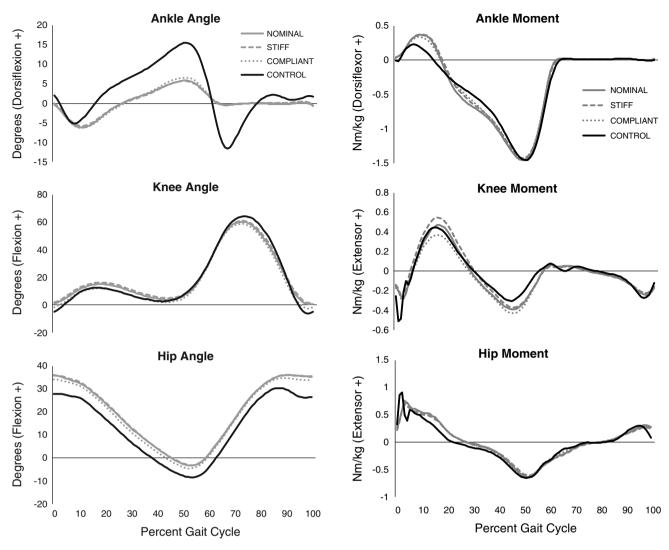


Fig. 3 Ankle, knee, and hip angles were averaged within subjects, then within groups.

Fig. 4 Ankle, knee, and hip internal joint moments were averaged within subjects, then within groups.

agreement with Kobayashi et al. [21], decreased resistance about the ankle resulted in less stance-phase knee flexion. These results are also in agreement with footwear literature that reports less knee flexion in soft midsole (ie, more compliant) running shoes [28]. In theory, an AFO with spring-like material properties that stores energy during midstance and returns the maximum amount of energy during late stance/preswing should be most beneficial to the user [3, 12, 42]. However, Bregman et al. [6] undertook a simulation approach to investigate how different stiffnesses affected walking biomechanics and found that the optimal (least metabolic cost) stiffness occurred when hip compensations were minimized. In the present study, no differences were found in hip kinematics or kinetics across strut stiffnesses potentially indicating that use of any of the three stiffnesses would result in similar metabolic costs. Overall, the biomechanical differences among struts were relatively small and a 40% range in stiffness did not drastically affect gait mechanics. In clinical practice, it is not possible to construct many AFOs to test optimal stiffness and clinicians and orthotists must make educated decisions based on available literature, prior experience, and patient needs. Although researchers are attempting to optimize dynamic AFO mechanical properties using modeling and simulation [6, 9], the results of this experimental study show that a range of stiffnesses may be equally beneficial to walking biomechanics.

Wearing a custom dynamic AFO after surgical treatment of limb trauma did not normalize gait to that of noninjured individuals and gait deficiencies remained across the lower extremity. Although knee ROM was lower in the patient group, the only differences in knee angle from control subjects occurred in swing and limb salvage patients did not adopt the stiff-kneed gait shown in previous reports



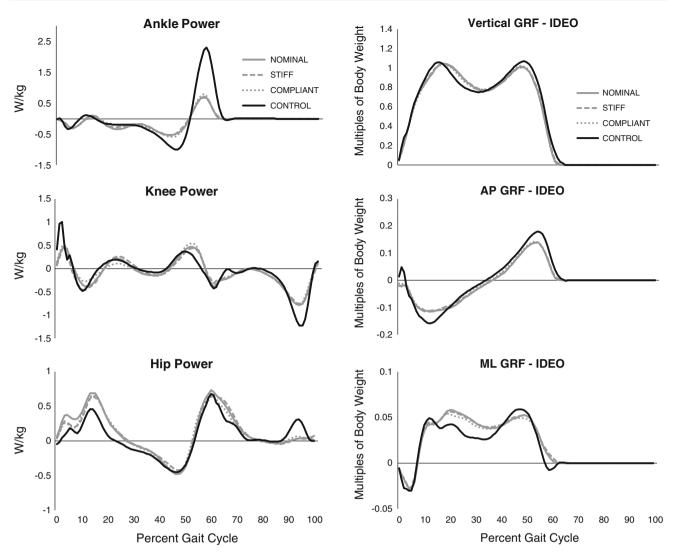


Fig. 5 Ankle, knee, and hip joint powers were averaged within subjects, then within groups.

Fig. 6 Ground reaction forces (GRFs) were averaged within subjects, then within groups. AP = anteroposterior; ML = mediolateral.

[10]. The patients also walked with greater hip flexion across the gait cycle. The stiff design of the IDEO along with impaired strength in the patients resulted in limited ankle plantarflexion. Many of the gait deviations such as decreased ankle motion and power were expected and are in agreement with previous literature on AFO use [5, 21]. To provide the support and stability necessary to achieve walking gait, some sacrifices in normative biomechanics must be made. Although no comparisons can be made to gait without the use of the IDEO, it is reasonable to expect that its use assisted and improved overall gait given the inability of some patients to walk without the device and the clinician and patient preference to use the device.

A more compliant AFO increases the stiffness at the knee through less knee flexion. However, AFO stiffness had few other effects on gait mechanics or on subjective preferences in patients with lower limb reconstructions. Patients may have readily adapted to the 40% stiffness range because walking did not stress the capabilities of the IDEO to the extent other dynamic activities such as running or jumping may have. Use of a semi-rigid, dynamic AFO inherently reduced the ROM and power capabilities at the ankle relative to controls and compensations at more proximal joints such as the knee resulted. Although none of the stiffness conditions restored all biomechanical gait parameters to those of control subjects, self-selected walking velocity was restored and previous reports have shown greater performance benefits with the IDEO compared with commercially available designs [33]. For walking, if a range of dynamic AFO stiffnesses may be appropriately prescribed, this may reduce the burden on the orthotist to experimentally test numerous designs to find the best stiffness characteristics for individual patients. Selecting a stiffer dynamic AFO may be preferred for



individuals who engage in high-impact activities (eg, running, jumping) to offer appropriate energy return with a lower risk of mechanical failure.

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